SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 1 3 2002

K013803
(Premarket Notification [510(k)] Number)

1. Applicant

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Corresponding Official:

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2. Device Name

Device trade or proprietary name: FlowGuard device

Common Name: Blood Flowmeter

Classification Name: Cardiovascular Blood Flowmeter, Class II, 870.2100

3. Predicate Devices

The FlowGuard device is substantially equivalent to a combination of the following devices:

Device	Manufacturer	510(k) No.
Blood Flow Meter Model HD-4200	Koven Technology, Inc.	K892707
EchoFlow BVM-1	EchoCath Inc.	K990642
Dynemo 3000	Sometec Inc.	K972798

4. Intended Use

The FlowGuard device is intended for non-invasive, peripheral vessel examinations and intraoperative examinations of blood flow measurements

5. Description of the Device

The FlowGuard is a dual-beam, angle-independent, pulse-wave Doppler ultrasound system used for non-invasive (peripheral vessel) and intra-operative volume blood flow measurements, including blood flow velocity and volume blood flow. In addition to the conventional Doppler (blood flow velocity) measurements, the FlowGuard technology utilizes special applications of ultrasound Doppler methods to obtain real-time measurements according to the definition of volume blood flow in target blood vessels. By definition, blood flow is the product of velocity and cross-sectional area. In other words, the volume blood flow is calculated by deriving flow velocity from the Doppler shift frequency using the basic standard formula and then multiplying the velocity by the cross-section area of the blood vessel..

6. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the FlowGuard device are substantially equivalent to the predicate devices cited above.

General Manager, Dr. Danny Manor

29.10.01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

Biosonix Ltd.
c/o Mr. Ahava M. Stein
A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL

Re: K013803
Trade Name: FlowGuard Device
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: November 11, 2001
Received: November 15, 2001

Dear Mr. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the FlowGuard Device, as described in your premarket notification:

Transducer Model Number V1004

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Kachi Enyinna at (301) 443-8262 ext. 162.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic blood flow measurements

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)				X						
Intra-operative Neurological				X						
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X						
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments: **Intra-operative (Specify): For direct application to exposed blood vessel (miniature, sterilizable transducer)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013805